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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,180	12/09/2005	Richard Joseph Fagan	C&R-108	1199
23557 7590 07/20/2007 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 07/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,180	<b>Applicant(s)</b> FAGAN ET AL.	
	<b>Examiner</b> Dong Jiang	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 46-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 46-66 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's preliminary amendment filed on 17 June 2005 is acknowledged and entered. Following the amendment, the original claims 1-45 are canceled, and the new claims 46-66 are added.

Currently, claims 46-66 are pending.

#### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 46, parts a) and i), and claims 65 and 66, drawn to a composition comprising a polypeptide.

Group II, claim(s) 46, parts b)-d) and i), drawn to a composition comprising a nucleic acid, a vector containing the nucleic acid, or a host cell thereof.

Group III, claim(s) 46, parts e), i) and n), drawn to a composition comprising an antibody to the polypeptide, and a kit thereof.

Group IV, claim(s) 46, part f), 1), and part i), drawn to a composition comprising a compound increasing the expression or activity of the polypeptide.

Group V, claim(s) 46, part f), 2), and part i), drawn to a composition comprising a compound decreasing the expression or activity of the polypeptide.

Group VI, claim(s) 46, parts g)-i), drawn to a composition comprising a compound binding the polypeptide without inducing the biological effect of the polypeptide.

Group VII, claim(s) 46, part j) in part, drawn to a composition comprising a vaccine of a polypeptide.

Group VIII, claim(s) 46, part j) in part, drawn to a composition comprising a vaccine of a nucleic acid.

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Group IX, claim(s) 46, parts k) and l), drawn to a composition comprising a kit containing nucleic acid probe and primer.

Group X, claim(s) 46, part m), drawn to a composition comprising a kit containing an array of nucleic acid.

Group XI, claim(s) 46, part o) in part, drawn to a composition comprising a transgenic non-human animal.

Group XII, claim(s) 46, part o) in part, drawn to a composition comprising a knockout non-human animal.

Groups XIII-XXIV, claim(s) 47 in part, and 52-61, drawn to a method of using one of the compositions in Groups I-XII in a method of diagnosing a disease.

Groups XXV-XXXVI, claim(s) 47 in part, and 48-51, drawn to a method of using one of the compositions in Groups I-XII in a method of treatment of a disease.

Groups XXXVII-XLVIII, claim(s) 47 in part, and 62, drawn to a method of using one of the compositions in Groups I-XII in a method of monitoring the therapeutic treatment of a disease.

Groups XLIX-LX, claim(s) 47 in part, 63 and 64, drawn to a method of using one of the compositions in Groups I-XII in a method of identifying or screening a compound.

The inventions listed as Groups I-LX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R., the main invention (Group I) in the instant application comprises the first-recited product, a composition comprising a polypeptide, and a variant or a fragment thereof. Although the nucleic acid of group II invention encodes the polypeptide of the main invention, and some of the methods of groups XIII-LX are directed to the methods of using the polypeptide, it is apparent that the polypeptide fragment is not itself an advance over the prior art because Ratcliffe et al. (US7,238,860) discloses a polypeptide, which comprises amino acids 12-19 of the present SEQ ID NO:10 with 100% sequence identity (see computer printout of the search results), thus renders the present claim 46, among the other, not novel. Therefore the technical feature of the polypeptide is not special, and thus, the groups do not share a special technical feature, and are not so linked by a single inventive concept under PCT Rule 13.1.

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Additionally, the other claimed products in groups III-XII are physically and functionally distinct chemical entities, which share neither structure nor function with that of Group I, and therefore, are not so linked to the main invention by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single general inventive concept. Further, some of the methods of groups XIII-LX do not correspond to the main invention, as they are neither a method of making, nor a method of using said polypeptide. Therefore, they are not considered to share a special technical feature with the main invention within the meaning of PCT Rule 13.2, and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121 and 372:

A. Elect one specific polypeptide sequence with SEQ ID NO: from the following: SEQ ID NO:10 or 12.

The polypeptides with different SEQ ID NO as recited in the claims do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of SEQ ID NOs represents a unique and structurally distinct chemical entity, and the SEQ ID NOs are unrelated, each to each other. Therefore, they do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-LX, and an election of the invention from Group A to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-LX nor A is species election requirement; rather, each of I-LX and A is a restriction requirement.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

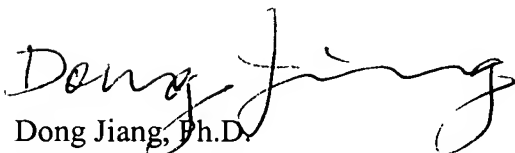
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**Advisory Information**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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7/16/07